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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,318	03/31/2004	Ron Wortley	11984.6	5172

27966 7590 07/13/2006
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,318

Applicant(s)

WORTLEY ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Claims 1-21, drawn to a tunneler, in the reply filed on 5 May 2006 is acknowledged. The traversal is on the ground(s) that each group of claims must be independent and distinct, and therefore there is no serious burden on the examiner because they do not have separate status in the art, as designated by the different classification of each group of claims, and that a multi-lumen tunneler cannot be used with a single lumen catheter. This is not found persuasive because restriction is proper when the claimed inventions are deemed to be either independent or distinct (see MPEP 803). Furthermore, the Office has shown a serious burden on the Examiner by classifying the two inventions in separate classes and subclasses, as shown in the previous office action, dated 17 April 2006: Invention I, drawn to a tunneler, is classified in class 623, subclass 1.11 while Invention II, drawn to a method for using a tunneler with a catheter, is classified in class 604, subclass 528. Finally, a multi-lumen tunneler can be used with a single lumen catheter, provided the width the catheter is adequate, and given that the width of a multi-lumen catheter will need to be a larger diameter to accommodate more than one tunneling lumen, a single lumen catheter with a larger diameter could be used to accommodate a two-lumen tunneler.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the image quality is not clear. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Nitinol is spelled incorrectly in paragraph [0030] in the specification.

Appropriate correction is required.

The disclosure is objected to because of the following: it is the examiner's position that applicant has invoked 35 U.S.C. 112, sixth paragraph in claims 2, 6, and 11, 17 by reciting "means for retaining," "first means for retaining," and "second means for retaining." Therefore the examiner requires the applicant to clarify the record by amending the specification to "explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element." MPEP 2181(IV). Please note that the MPEP clearly states that "[e]ven if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant

to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)..."
(MPEP 2181(IV)). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "a shaft" in line 1. There is insufficient antecedent basis for this limitation in the claim because it is not clear which shaft the Applicant is referring to.

Regarding Claim 10, it is unclear what Applicant wishes to claim. It is not possible for a sheath to cover a portion of itself. Furthermore, for the purposes of examination, the second instance of the word "the" will be read as "that" and the second instance of the word "sheath" will be read as "shaft" so that Claim 10 will be examined as: The system of Claim 9, further comprising a sheath that covers the portion of the tip and shaft that are connected. Further, as a result of this interpretation, Claim 10 recites the limitation "the shaft" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate action is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (US Patent Application 2002/0099327).

Regarding Claim 1 and 5, Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20).

Regarding Claims 2, 3, 6, and 7, Wilson'327 discloses a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (21a) located on the outside of shaft members (14, 16).

Regarding Claims 4 and 8, Wilson'327 discloses that the difference in the lengths of the shaft members (14, 16) is up to 20 percent (Figure 1).

Regarding Claim 9, Wilson'327 discloses a shaft (12) that is removably connected to tip (20).

Regarding Claim 10, Wilson'327 discloses a sheath (34) that covers the portion of the shaft (12) and the tip (20) that are connected.

Regarding Claims 11 and 12, sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring

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for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (21a) exist on shaft (21).

Regarding Claim 13, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Regarding Claim 14, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Regarding Claim 15, Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20). Shaft (12) is removably connected to tip (20) and sheath (34) covers the portion of the tip (20) and shaft (12) that are connected.

Regarding Claim 16, Wilson'327 discloses that a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (21a) located on the outside of shaft members (14, 16).

Regarding Claims 17 and 18, sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (21a) exist on shaft (21).

Regarding Claim 19, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Regarding Claim 20, the retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durand (US Patent 5,405,329) in further view of Wilson'327.

Durand'239 teaches the use of a multi-lumen catheter (Figure 1) and a distal end (4) that can be used as a tunneler (column 3, lines 19-34). Durand'239 does not teach that the tunneler portion contains multiple shafts.

Wilson'327 teaches a multi-lumen catheter that is capable of use as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20).

It would have been obvious to one skilled in the art at the time the invention was made to modify the device made by Durand'239 with a multi-lumen catheter in order to

keep the two catheters separate through the tunnel and prevent having them twist together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER